

专利合作条约

PCT

专利性国际初步报告

(PCT 第II章)

(PCT 36 和细则 70)

REC'D 25 OCT 2005

WIPO

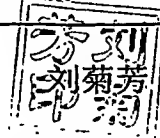
PCT

申请人或代理人的档案号 OP040074P	关于后续行为 参见 PCT/IPEA/416 表	
国际申请号 PCT/CN2004/001411	国际申请日(日/月/年) 03.12 月 2004 (03.12.2004)	优先权日(日/月/年) 05.12 月 2003 (05.12.2003)
国际专利分类(IPC)或者国家分类和 IPC 两种分类 IPC ⁷ : A61K9/48, A61K31/34		
申请人 石药集团中奇制药技术(石家庄)有限公司 等		

1. 本报告是国际初步审查单位根据条约 35 做出的国际初步审查报告,并依照条约 36 将其传送给申请人。
2. 本报告共计3页,包括扉页。
3. ☐ 本报告还有附件,
 - a. ☐ (传送给国际局和申请人)共计 _____ 页,包含
☐ 修改后的并且作为本报告基础的说明书修改页、权利要求书修改页和/或附图修改页,和/或对
 本国际初步审查单位所做出的更正页(见 PCT 细则 70.16 和行政规程 607)。
☐ 国际初步审查单位认为修改超出原始公开范围的取代页,参见第 I 栏第 4 项和补充栏。
 - b. ☐ (传送给国际局) 共计 (指明电子载体的类型和数量) _____, 包含有在与序列表有关的补充栏中
 指明的电子形式的序列表和/或与其相关的表格。(行政规程 802)

4. 本报告包括关于下列各项的内容:

- I ☒ 报告的基础
- II ☐ 优先权
- III ☐ 不做出关于新颖性、创造性和工业实用性的意见
- IV ☐ 缺乏发明的单一性
- V ☒ 按条约 35(2)关于新颖性、创造性或工业实用性的理由;支持这种意见的引证和解释
- VI ☐ 引用的某些文件
- VII ☐ 国际申请中的某些缺陷
- VIII ☐ 对国际申请的某些意见

提交要求书的日期 27.6 月 2005 (27.06.2005)	完成本报告的日期 05.9 月 2005 (05.09.2005)
中华人民共和国国家知识产权局 IPEA/CN 中国北京市海淀区西土城路 6 号(100088) 传真号: (86-10)62019451	受权官员  电话号码 (86-10)62085085

I. 报告的基础

1. 关于语言, 本报告将基于:

☒ 申请提出时使用的语言。

☐ 该申请的_____语言译文, 提供该种语言的译文是

☐ 为了国际检索而提交的译文所使用的语言(细则 12.3 和 23.1 (b))。

☐ 为了国际申请的公布而提交的译文所使用的语言(细则 12.4)。

☐ 为了国际初步审查而提交的译文所使用的语言(细则55.2和/或55.3)。

2. 关于国际申请中各个部分, 本报告基于(申请人为答复受理局根据条约 14 所发通知而提交的替换页, 在本报告中视为“原始提交”的文件, 不作为本报告的附件)

☒ 原始提交的国际申请。

☐ 说明书, 第_____页 原始提交的, _____初审单位收到的, _____初审单位收到的。

☐ 权利要求, 第_____页, 原始提交的, _____初审单位收到的, 第_____页, 按条约 19 条修改的(附有说明), _____初审单位收到的, 第_____页 _____初审单位收到的。

☐ 附图, 第_____页, 原始提交的。第_____页*, _____初审单位收到的, 第_____页*, _____初审单位收到的。

☐ 序列表和/或相关表格——参见与序列表有关的补充栏。

3. 修改导致以下内容的删除:

☐ 说明书, 第_____页
☐ 权利要求, 第_____项
☐ 附图, 第_____页, 图_____
☐ 序列表(具体说明)_____
☐ 与序列表相关的表格(具体说明)_____

4. ☐ 由于本报告附件的(某些)修改, 如下所列, 被认为超出了原始公开的范围, 如补充栏所示, 因此本报告是按照没有修改的情况做出的(细则 70.2(c))。

☐ 说明书, 第_____页
☐ 权利要求, 第_____项
☐ 附图, 第_____页, 图_____
☐ 序列表(具体说明)_____
☐ 与序列表相关的表格(具体说明)_____

*如果第 4 项适用, 一些或全部的文件页可能做出“被取代”标记。

V. 按条约 35 (2) 关于新颖性、创造性或工业实用性的意见；支持这种理由的引证和解释

1. 意见

新颖性(N)	权利要求 1-11	是
	权利要求	否
创造性(IS)	权利要求 1-11	是
	权利要求	否
工业实用性(IA)	权利要求 1-11	是
	权利要求	否

2. 引证和解释 (细则 70.7)

1) 对比文件: CN1375288A (周桂荣) 23.10.2002

CN1257706A (中国医学科学院药物研究所) 28.06.2000

WO95001574A (MOBIUS CONSULTANCY PIY LTD (AU)) 05.01.1995

2) 新颖性 (Art.33(2) PCT) 和创造性 (Art.33(3) PCT)

D1 公开了可制成注射液、输注液和各种口服剂型, 含治疗脑血管疾病有效量的丁苯酞和磷脂乳化而成的脂质体 (参见全文); D2 公开了丁苯酞在制备抗血栓形成及抗血小板聚集药物中的应用 (参见全文); D3 公开了治疗炎性疾病的方法及治疗剂, 其中所述化合物包含丁苯酞 (参见全文)。这些对比文件都没有公开通过选择本发明中的特定辅料而将丁苯酞制成软胶囊的技术方案或有关技术启示, 因此权利要求 1-11 具备新颖性, 而且由于权利要求 1-11 中的技术方案是对本领域的技术人员来说是非显而易见的, 因此这些权利要求具备创造性。

3) 工业实用性 (Art.33(4) PCT)

权利要求 1-11 请求保护的包合物及其制备方法都可在工业上实施, 因此具备工业实用性。

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN2004/001411

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages • _____ received by this Authority on _____
- pages • _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages • _____ as amended (together with any statement) under Article 19
- pages • _____ received by this Authority on _____
- pages • _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages • _____ received by this Authority on _____
- pages • _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN2004/001411

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement:

Novelty (N)	Claims <u>1-11</u>	YES
	Claims _____	NO
Inventive step (IS)	Claims <u>1-11</u>	YES
	Claims _____	NO
Industrial applicability (IA)	Claims <u>1-11</u>	YES
	Claims _____	NO

2. Citations and explanations (Rule 70.7)

1) Reference is made to the following documents:

D1: CN1375288A (ZHOU Guirong) 23.10.2002

D2: CN1257706A (CHINESE ACAD MEDICAL SCI INST MEDICAL MA) 28.06.2000

D3: WO9500157A (MOBIUS CONSULTANCY PTY. LTD) 05.01.1995

2) Novelty (Art.33(2) PCT) and inventive step (Art.33(3) PCT):

D1 disclosed a liposome composed of butylphthalide and phosphatide emulsification for treatment of cerebrovascular disease (see the whole); D2 disclosed an application of butylphthalide in preparing medicines for curing thrombosis and thrombocyte coagulation (see the whole); D3 disclosed a method for the treatment of an inflammatory complaint and the therapeutic agent thereof including butylphthalide and filler (see the whole). The subject-matter of claim 1-11 is thus novel in view of the available prior art since no document disclosed the soft capsule involving the specific diluent and coating material. Nor did the documents give a suggestion or hint to come to the solution as set out in claims 1-11, and therefore they are considered as involving an inventive step.

3) Industrial applicability (Art.33(4) PCT):

The subject-matter of claims 1-11 concerning clathrate and the corresponding preparation are industrially applicable under Article 33(4) PCT.